

REMARKS/ARGUMENTS

In response to the Second Restriction Requirement mailed on November 17, 2003, Applicants submit herewith:

- a) a Preliminary Amendment; and
- b) a Response to the Second Restriction Requirement.

Please consider the following remarks.

a) Preliminary Amendment

a1) Status of the Claims

Claims 1-48 are pending in the present application. Claims 3, 5, 8, 11-16, 20-23, 27, 29, 31, 34-36, 38, 40, 42-44, and 47 are amended.

a2) The Invention

The present invention provides a family of dendrimers that are useful as supports, vectors, carriers or delivery vehicles for a variety of compounds in biomedical and technological applications. In particular, the macromolecules may be used for the delivery of drugs, genetic material, imaging components or other functional molecule to which they can be conjugated. An additional feature of the macromolecules is their ability to be targeted for certain organs, tumors, or types of tissues.

a3) The Amendments

Claim 3 is amended in order to place the claim in proper Markush format. This amendment is correcting a minor typographical error.

Claim 5 is amended in order to provide a proper antecedent basis for the term 'anhydride' which is described in claim 1. This amendment is correcting a minor typographical error.

Claim 8 is amended in order to place the claim in proper Markush format. This amendment is correcting a minor typographical error.

Claim 36 is amended in order to provide a proper antecedent basis for the term 'biological compartment' which is described in claim 33. This amendment is correcting a minor typographical error.

Claims 11-16, 20-23, 27, 29, 31, 34-36, 38, 40, 42-44, and 47 are amended in order to correct errors in claim dependencies. In each of the above claims, the originally listed claim dependency was off from the correct claim dependency by the number two. In most cases, the changes correct obvious errors in claim dependency. For example, method claim 40 should be dependent on method claim 39, and not upon biological compartment claim 37 as originally listed. Therefore, these amendments are correcting minor typographical errors.

b) Response to Second Restriction Requirement

On Friday, December 5, 2003, Applicants discussed the Second Restriction Requirement with Examiner Trinh in a telephone conference. At that time, Applicants noted that the Grouping Scheme of the claims was confusing and asked the Examiner if Applicants could suggest a Grouping Scheme that was more in keeping with Patent Office Practice. While Examiner Trinh insisted that we proceed with a Response (with traversal) to the Second Restriction Requirement, he suggested that we could propose a new grouping of the claims in the traversal. Therefore, the Response to the Second Restriction Requirement is divided into three sections. The first section elects a Restricted Group based upon Examiner Trinh's Grouping Scheme. The second section elects a Species within this Restricted Group. The third section contains a traversal of the Second Restriction Requirement, along with Applicant's Proposed Grouping Scheme.

b1) Election of Restricted Group

The Examiner has restricted the pending claims into eleven Groups. In response to the Second Restriction Requirement, Applicants elect the claims of Group IX for prosecution on the merits. Applicants respectfully traverse the Second Restriction Requirement and propose an Alternative Grouping Scheme (see below).

b2) Election of Species

From claim 8 in Group IX, Applicants elect the following species as a starting point for the Examiner's prior art search: A is a star polyalkylene oxide, R⁵ is H, and R⁶ is a therapeutic agent.

b3) Traversal and Alternative Grouping Scheme

b3) i) Traversal

Applicants respectfully traverse the Second Restriction Requirement on three grounds. The first concerns the extraordinary nature of the Examiner's action. The second concerns the Examiner's lack of explanation for the necessity of his action. The third concerns the lack of internal consistency in the Examiner's present Grouping Scheme.

In issuing this Second Restriction Requirement, the Examiner has taken an action that is not sanctioned by the CFR or the MPEP. On May 9, 2003, a First Restriction Requirement was issued for this patent application. Applicants timely responded on June 5, 2003. On November 17, 2003, the Examiner unilaterally withdrew the First Restriction Requirement and issued a Second Restriction Requirement. While the issuance of a Second Restriction Requirement itself is not forbidden, such an action is taken to build upon the First Restriction Requirement. There is no section of the CFR or the MPEP that enables the Examiner to unilaterally withdraw a Restriction Requirement. If such a section exists, Applicants respectfully request that the Examiner bring it to the Applicants' attention.

In light of the unique nature of the Examiner's action, Applicants were very interested in the reasons for the decision. However, the following is the Examiner's only comment on the subject:

The restriction requirement as set forth in paper no. 4 (dated 05-09-03) is withdrawn. Thus, applicant's response filed on 06-09-03 had (sic) become moot. A new restriction requirement is hereby made.

Second Restriction Requirement, mailed 11/17/03

So, in addition to taking the unprecedented action of unilateral withdrawal, the Examiner has taken this action without describing the deficiencies in the First Restriction Requirement. Therefore, Applicants respectfully request an explanation of the reasons why the First Restriction Requirement was deficient, and how the Grouping Scheme in the Second Restriction Requirement addresses these deficiencies.

Finally, Applicants traverse the present Grouping Scheme proposed by the Examiner, as it divides the claims into eleven Groups which are inconsistent with one another. While virtually all of the Groups contain contradictions, for the sake of brevity, Applicants only address the problems with Group IX. This was the Group selected above for prosecution by the Applicants.

Group IX includes claims 8, 9, 10, 36, 37, and 38, and contains several inconsistencies. The first involves the claim groupings. Claims 8, 9, and 10 are all directed to dendrimers which are substantially free of urea side products. Claims 36, 37, and 38 are directed to biological compartments. Applicants are unclear about the reasoning the Examiner used to group the claims in this manner, as opposed to some other manner. Applicants therefore respectfully request an explanation from the Examiner as to how he believes these claims are related.

The second inconsistency involves the Examiner's characterization of the Group. The Examiner states that Group IX is "drawn to wherein A is poly(alkylene oxide)". However, the last member of Group IX, claim 38, lacks any reference to polyalkylene oxides. Therefore, Group IX contains claims which do not fit the Examiner's description of the Group.

For the two reasons above, the Grouping Scheme employed by the Examiner in this Second Restriction Requirement is flawed. Since this will only serve to make the prosecution of this patent application more onerous, Applicants respectfully propose the following Alternative Grouping Scheme.

b3) ii) Alternative Grouping Scheme ("AGS")

In this AGS, the claim set is divided into four groups:

- I. Claims 1-7, drawn to anhydride compounds;
- II. Claims 8-31, drawn to dendrimer compounds;
- III. Claims 32-38, drawn to biological compartments; and
- IV. Claims 39-48, drawn to methods of making and methods of using the compounds.

Because this Scheme is demarcated along the general classes of the invention, all the claims within each group are related to each other, thus alleviating the inconsistencies found in the Examiner's Grouping Scheme.

In this AGS, Applicants elect the claims of Group II (claims 8-31) for prosecution on the merits.

From claim 8 in Group II, Applicants elect the following species as a starting point for the Examiner's prior art search: A is a star polyalkylene oxide, R⁵ is H, and R⁶ is a therapeutic agent.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Appl. No. 09/963,858
Amdt. dated February 17, 2004
Reply to Office Action of November 17, 2003

PATENT

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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